

REMARKS

Claims 1 - 8 are pending in the present application. Claim 9 has been cancelled. The following rejections are at issue and are set forth by number in the order in which they are addressed:

1. Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite; and
2. Claims 1 - 8 are rejected under 35 U.S.C. §112, first paragraph, as allegedly failing to comply with the written description requirement.

1. The Claims are Definite

Claim 8 is rejected under 35 U.S.C. §112, second paragraph, as allegedly being indefinite. The Federal Circuit has made it clear that definiteness of claim language must be analyzed, not in a vacuum, but in light of 1) the content of the particular application disclosure, 2) the teachings of the prior art, and 3) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. See, e.g., *In re Marosi*, 710 F.2d 799, 218 USPQ 289 (Fed. Cir. 1983); *Rosemount, Inc. v. Beckman Instruments, Inc.*, 727 F.2d 1540, 221 USPQ 1 (Fed. Cir. 1984); and *W.L. Gore & Assocs., Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983). Applicants respectfully submit that the claims are definite as originally drafted.

The Examiner argues that “Claim 1 requires a gene construct yet dependent claim 8 requires that only a promoter be used” The Examiner is mistaken on three counts. First, Claim 1 specifies an “irritant responsive reporter gene construct” as opposed to just a gene construct as alleged by the Examiner. Second, Claim 8 specifies that the “irritant responsive reporter gene construct comprises a promoter” (Emphasis added). Thus, Claim 8 does not specify a promoter only, it species that a promoter is part of the reporter gene construct. In other words, the promoter drives expression of the reporter gene in the construct. Third, as just mentioned, the reporter gene construct includes a reporter gene. Thus, it is clear as to what gene is being expressed – a reporter gene. As can be seen, the Examiners arguments are misplaced and claim 8 is clear to person of ordinary skill in the art. Applicants respectfully request that this

rejection be withdrawn.

2. The Claims Comply with the Written Description Requirement

On page 2 of the Office Action, the Examiner indicates that the applicants did not submit a declaration from Dr. Allen Comer. Applicants respectfully submit that the Declaration was filed with the previous response. The Examiner's attention is directed to Tab 1 of the appendix to this response. The post card attached at Tab 1 indicates that the Comer Declaration was filed with the previous response. For the Examiner's convenience, the Declaration is attached at Tab B. As the Examiner will notice, the Declaration contains a certificate mailing indicating that it was submitted to the Patent Office on December 13, 2004. Because this Declaration was not considered by the Examiner, it is necessary to repeat the arguments that were presented in the Applicant's prior response and which were not considered by the Examiner.

As held by the Federal Circuit in *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996) the adequate written description requirement:

serves "to ensure that the inventor had possession, as of the filing date of the application relied on, of the specific subject matter later claimed by him; how the specification accomplishes this is not material." *In re Wertheim*, 541 F.2d 257, 262, 191 U.S.P.Q. (BNA) 90, 96 (CCPA 1976). In order to meet the adequate written description requirement, the applicant does not have to utilize any particular form of disclosure to describe the subject matter claimed, but "the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 U.S.P.Q.2D (BNA) 1614, 1618 (Fed. Cir. 1989) (citation omitted). Put another way, "the applicant must . . . convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention." *Vas-Cath*, 935 F.2d at 1563-64, 19 U.S.P.Q.2D (BNA) at 1117.

Thus, determining whether the written description requirement is satisfied requires reading the disclosure in light of the knowledge possessed by those skilled in the art. That knowledge can be established by affidavits of facts composed by experts, and by reference to publications available to the public prior to the filing date of the application. See *In re Alton*, 76 F.3d 1168, 37 USPQ2d 1578 (Fed. Cir. 1996); *In re Lange*, 644 F.2d 856, 209 USPQ 288 (CCPA 1981).

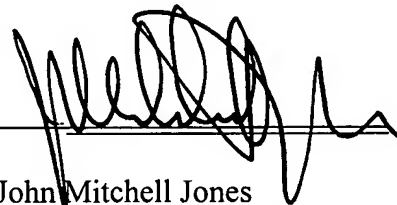
The Examiner alleges that the two genes specifically identified in the application are insufficient to describe a genus. As support for this argument, the Examiner cites to *Eli Lilly*, 199 F.3d at 1568. The Examiner's reliance on *Eli Lilly* is misplaced. The claims of the present invention are not specifically directed to newly discovered genetic elements, as were the claims that were invalidated in *Eli Lilly*. In contrast, the presently claimed invention can be practiced with known promoters from known irritant responsive genes. As described in the accompanying Declaration of Dr. Allen Comer, a number of these genes and promoters were known as of the March 2001 priority date of the application. Moreover, the specification describes how to use these promoters in assays to determine which promoters are useful and which are not. This is factual evidence of what was known to those of skill in the art. In *Eli Lilly*, there was no evidence that other insulin cDNA sequences were known in the art. If such sequences were known, the invention would have been anticipated, not have lacked an adequate written description.

As described above, the case law is clear on the point that affidavits can be introduced that factually establish what was known in the art by reference to prior publications. This is precisely what has been done in the present case. The fact that the claims also encompass unknown sequences is moot in light of this factual evidence that many promoters were known which could be utilized in the present invention. As such, Applicants respectfully submit that those of skill in the art would recognize that the Applicants were in possession of the claimed invention because those of skill in the art would have easily recognized that other promoters than those exemplified in the specification could be used to practice the invention. As such, Applicants respectfully request that this basis for rejection be removed and the claims passed to allowance.

CONCLUSION

All grounds of rejection and objection of the Office Action of March 30, 2005 having been addressed, reconsideration of the application is respectfully requested. It is respectfully submitted that the invention as claimed fully meets all requirements and that the claims are worthy of allowance. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicant encourages the Examiner to call the undersigned collect at (608) 218-6900.

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John Mitchell Jones
Registration No. 47,436

MEDLEN & CARROLL, LLP
101 Howard Street, Suite 350
San Francisco, California 94105
608.218.6900